K111786 (pg. 1 of 3)

JAN 2 6 2012

Summary of Safety and Effectiveness
Hoffmann 3 Modular External Fixation System

Proprietary Name:	Hoffmann 3 Modular External Fixation System
Common Name:	External Fixation System
Classification Name and Reference:	Single Multiple component metallic bone fixation appliance and accessories, 21 CFR §888.3030
Regulatory Class:	Class II
Product Codes:	87 KTT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Components
Predicate Devices:	Hoffmann II MRI External Fixation System
For Information contact:	Estela Celi, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-6038 estela.celi@stryker.com
Date Prepared:	October 5, 2011

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the Hoffmann 3 Modular External Fixation System as a line extension to the currently marketed Hoffmann II MRI External Fixation System. The Hoffmann 3 Modular External Fixation System consists of Rods, Posts, Couplings, Clamps and Pins that can be combined to construct different frame configurations that are MR conditional. The components for the subject device where manufactured from a variety of materials including austentic steel, titanium, aluminum and a Vectran coating. This line extension is intended to add additional components for connecting rods and fixed posts, design and material modifications to the couplings, pin clamp, rods and posts. Although the Hoffmann II MRI External Fixation System will continue to be marketed, the Hoffmann 3 Modular External Fixation System will be available with additional components for connecting rods and fixed posts and include design and material modifications to the couplings, pin clamp, rods and posts.

Intended Use

The Hoffmann 3 Modular External Fixation System is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

The indications for use of external fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

Indications for Use

The Hoffmann 3 Modular External Fixation System components are external fixation frame components for use with the components of the Hoffmann II MRI and Hoffmann II Compact MRI External Fixation Systems, in conjunction with Apex Pins. It is intended to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

Summary of Technologies

Device comparisons showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the Hoffmann II MRI System, predicate device, previously cleared in K051306, K053038, and K053472. The subject Hoffmann 3 Modular External Fixation System components share the same intended use and basic design concepts as that of the currently available Hoffmann II MRI External Fixation System. Mechanical testing demonstrated comparable mechanical properties to the predicate components. Testing in a Magnetic Resonance Environment established that the Hoffmann 3 Modular External Fixation System could be safely used in Magnetic Resonance Imaging under predetermined conditions.

Non-Clinical Testing

Non-clinical laboratory testing was performed on the Hoffmann 3 Modular External Fixation System to determine substantial equivalence. The following testing was performed:

- Frame Testing
- Bending Strength Testing
- Torsion Strength Testing
- Pull-Out Testing
- Rotation Strength Testing

Magnetic Resonance Environment Testing

- Radio Frequency Heating Testing
- Force and Torque Testing
- Artifact Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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% Ms. Estela Celi
Regulatory Affairs Associate
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Mahwah, New Jersey 07430

JAN 2 6 2012

Re: K111786
Trade/Device Name: Hoffmann 3 Modular External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: KTT
Dated: January 9, 2012
Received: January 10, 2012

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

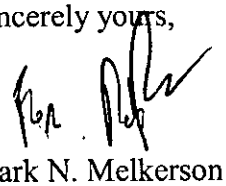
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111786

Device Name: Hoffmann 3 Modular External Fixation System

Indications for Use:

The Hoffmann 3 Modular External Fixation System components are external fixation frame components for use with the components of the Hoffmann II MRI and Hoffmann II Compact MRI External Fixation Systems, in conjunction with Apex Pins. It is intended to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rods, casts or other means of internal fixation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111786